



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

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San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

**VIA INT'L FEDERAL EXPRESS**

June 25, 2001

Our Reference: 2954103

Alan D. Smithwick, President  
Pacific Network, Inc.  
Dba Sea Pak Corporation  
1026 Cabras Highway  
Warehouse 1, End Bay  
Piti, Guam 96925

**WARNING LETTER**

Dear Mr. Smithwick:

We inspected your seafood processing facility on April 9, 11, and 17, 2001. We conducted this inspection to determine your compliance with FDA's Seafood HACCP regulations, 21 Code of Federal Regulations (21 CFR 123) and the Good Manufacturing Practice (GMP) requirements for foods (21 CFR 110).

We found that your firm has serious HACCP deviations. These deviations cause your histamine forming fish species such as tuna and marlin to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fish have been prepared, packed, or held under insanitary conditions, whereby they may be rendered injurious to health. We listed the deficiencies on a Form FDA 483 and discussed them with you at the conclusion of the inspection. Your serious HACCP deviations are as follows:

1. You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). However, your firm's HACCP plan for **Tuna** does not list the food safety hazard of *Clostridium botulinum* toxin formation as a result of time/temperature abuse in refrigerated vacuum packed fish. We are aware that your firm exports the refrigerated vacuum packed tuna only to the European Union countries. However, in order to claim exemption from the seafood HACCP regulations, a firm must meet the requirements of Section 801(e)(1) of the Food, Drug, and Cosmetic Act (the Act) for product intended for export. If you do not meet the exemption criteria and do not comply with the HACCP regulation, the exported products manufactured by your firm is deemed adulterated. We are enclosing a copy of Section 801(e) of the Act for your reference.

2. You must have a HACCP plan that lists the critical limits that must be met, to comply with 123.6(c)(3). However, your firm's HACCP plan for **Histamine Forming Species including Tuna and Marlin** lists a critical limit at the Receiving CCP that is not adequate to control histamine formation as a result of time/temperature abuse in scombroid fish received directly from the harvester.

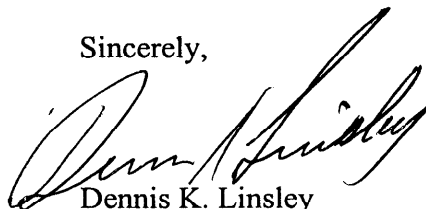
We may take further regulatory action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union countries if you do not correct these deviations.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You may wish to include in your response documentation such as time/temperature monitoring records, sanitation records, revised HACCP plans, etc. If you cannot complete all the corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,



Dennis K. Linsley

Director

San Francisco District

Enclosure